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10/050,238	01/16/2002	Michael Paul Aronson	J6699/1(C)	6809

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UNILEVER INTELLECTUAL PROPERTY GROUP
700 SYLVAN AVENUE,
BLDG C2 SOUTH
ENGLEWOOD CLIFFS, NJ 07632-3100

EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,238	ARONSON ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/12/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-7,9-13,15-17 and 19-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *4-7,9-13,15-17 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment received on 05/12/2006, wherein new claims 22-23 have been added, and claim 1 has been canceled.

Claims 4-7, 9-13, 15-17, and 19-23 are pending, and examined herein.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-7, 9-13, 15-17, 19-23 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular compounds or agents for organic stabilizer disclosed in the specification (see page 7-17 of the specification herein) in composition herein to be made by the claimed process, does not reasonably provide enablement for any compounds having functional properties recited in the claims herein.

This recitation "organic stabilizer" is seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required

undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a process for making a cosmetic composition.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since the broadest claim (i.e., claim 22) reads on any compounds having functional properties recited in the claims herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California B. Eli Lilly* and Co. 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405 (emphasis added), and that "It does not define any structural features commonly possessed by members of the genus

that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added).

In the instant case "a organic stabilizer" recited in the instant claims are purely functional distinction. Hence, this functional recitation read on any compounds that might have the recited functions. However, the specification merely provides those particular compounds for functional compounds for the composition to be made by the claimed process (see page 12 of the specification).

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (Genera Electric Company v. Wabash Appliance Corporation et al. 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: the instant claimed invention is highly unpredictable as discussed below:

In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California B. Eli Lilly and Co*. Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill

in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the cosmetic compositions herein to be applied to the skin of the host, a topical administration.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, and side effects, especially serious toxicity that may be generated by drug-drug interactions when and/or after applying to skin, a topical administration of the combination of any compounds represented by "a organic stabilizer" which may encompass more than a thousand compounds. See text book Goodman & Gilman's The Pharmacological Basis of Therapeutics" regarding possible drug-drug interactions (9th ed 1996) page 51 in particular. This book teaches that "The frequency of significant beneficial or adverse drug interactions is unknown" (see the bottom of the left column of page 51) and that "Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed" and that "The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences" (see the right column of page 51) (emphases added). In the instant case, in the absence of fully recognizing the identity of the members genus herein, one of skill in the ad would not be able to fully predict possible adverse drug-drug interactions occurring with many combinations of any compounds having claimed functional properties in the pharmaceutical or cosmetic compositions

herein to be administered to a host. Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

As discussed above, only those particular compound for functional compounds employed in the composition herein is disclosed in the specification. Moreover, it is noted that the specification merely provide those particular compositions comprising particular compounds in working examples (see page 38-61). Thus, the evidence in the examples is not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients in the claimed composition to be made by the claimed process. See MPEP 716.02(d).

Thus, the specification fails to provide sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors, the case University of California v. Eli Lilly and Co. (CAFC, 1997) and In re Fisher (CCPA 1970) discussed above, to practice

the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test all compounds having the functional properties encompassed in the instant claims and their combinations employed in the claimed compositions to be administered topically to the skin of a host, with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-7, 9-13, 15-17, 20, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glenn, Jr et al. (WO 9625144, equivalent to US 6,080,708), in view of Tsaur (US 5,759,969, PTO-892) .

Glenn, Jr et al. teaches the process for making a cleansing/moisturizing dual composition (a wet-skin treatment composition) which is an oil-in-water emulsion, wherein (a) an aqueous phase comprising water and dispersion stabilizer such as trihydroxystearin having the formula (i) (according to the formula therein, the molecular weight is deemed lower than 1000 Daltones and capable of forming a network in the aqueous phase), which is a fatty acid ester or C14-C22 acyl derivative as the instantly claimed, or silicas (see US 6,080,708, abstract; col.4, line 46 to col.6) or polymeric stabilizers herein; (b) a structured oil phase (a lipid phase) comprising triglycerides and a structurant in about 75% by wt of that forms a stable 3-dimentional network

comprising solid fatty esters, fatty alcohols, wax, petrolatum, with droplet size 0.1-100 microns, having viscosity within the instant claimed (see col.10-16). Glenn et al. also teaches that the aqueous phase of oil-in-water emulsion comprises from about 1 part to about 30 parts of surfactant selected from the group consisting of anionic surfactants, nonionic surfactants, cationic surfactants, amphoteric surfactants, and mixtures thereof. The emulsions containing 0.5 parts to 8 parts C8-C14 soap i.e anionic surfactant wherein the soap has a counterion selected from K and N(CH2CH2OH)3, in addition to synthetic surfactant such as amphoteric, nonionic, and cationic are taught as preferred embodiments. See abstract; column 6, lines 3-60, lines 44-49; column 24, claim 20-24. It is also disclosed, that the size of lipid droplets within the emulsion ranges from 0.1-100 microns. See column 13, lines 59-60. An oil-in-water composition comprising structurant, myristic alcohol; oil such as liquid cottonseed; organic dispersion stabilizer, trihydroxystearin is disclosed. See column 18, Examples 1-4.

Glenn, Jr et al. also clearly teaches the stepwise process for making the composition therein (see col 17, lines 25-65), including measuring skin retention and emulsions tests at 35 °C (see col.16, line 40-col.17, line 23). The reference also teaches that antimicrobial agents (preservative) and EDTA (chelating agent) and an essential oil are used. See col. 9, line 49 - col.10, line 37; col. 17, lines 42-45. See instant claims 37-38.

Glenn, Jr et al. does not expressly disclose the step of passing structured oil-in-water predispersion through a screen having an opening of up to about 2000 micrometers as claimed herein.

Tsuar teaches a process for making aqueous liquid cleanser compositions comprising large hydrogel particles with particle size obtained by passing through in-line-screen. See abstract; column 4, lines 53-65. A batch process such as an overhead mixer or a flotation machine or a continuous process such as a two fluid coextrusion nozzle, an in-line injector, an in-line mixer or an in-line screen can be used to make the hydrogel dispersion. See example 15, wherein a skin care lotion is obtained by passing the aqueous composition containing the petrolatum hydrogel noodles through a screen having mesh size 200 um to form the hydrogel dispersions.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to pass oil-in-water predispersion through a screen having an opening of up to about 2000 micrometers to make the wet skin treatment composition because 1) Tsuar teaches that cleansing hydrogel dispersion composition comprising hydrogel particles of specific particle size are obtained by passing the predispersion through screen having mesh size 200 um.

Thus, One having ordinary skill in the art at the time the invention was made would have been motivated to pass oil-in-water predispersion through a screen having an opening of up to about 2000 micrometers with reasonable success of obtaining a wet skin treatment oil-in-water composition with lipid droplet size in the range taught by Glenn et al., i.e the size of lipid droplets within the emulsion ranges from 0.1-100 microns.

Claims 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glenn, Jr et al. (WO 9625144, equivalent to US 6,080,708), in view of Tsaur as applied to claims 4-7, 9-13, 15-17, 20, 22-23 above, and further in view of Lochhead et al. (US 5,004,598, PTO-1449).

Glenn, Jr et al. as discussed above teaches the process for making a cleansing/moisturizing dual composition (a wet-skin treatment composition) which is an oil-in-water emulsion, wherein (a) an aqueous phase comprising water and dispersion stabilizer such as trihydroxystearin, or silicas or polymeric stabilizers herein; (b) a structured oil phase (a lipid phase) comprising triglycerides and a structurant in about 75% by wt of that forms a stable 3-dimentional network comprising solid fatty esters , fatty alcohols, wax, petrolatum, with droplet size 0.1-100 microns, having viscosity within the instant claimed. Glenn et al. also teaches that the aqueous phase of oil-in-water emulsion comprises from about 1 part to about 30 parts of surfactant selected from the group consisting of anionic surfactants, nonionic surfactants, cationic surfactants, amphoteric surfactants, and mixtures thereof.

Glenn et al. does not teach the process for making a cleansing/moisturizing composition without a surfactant.

Lochhead et al. teach a process for making cleansing/moisturizing oil-in-water emulsions without a surfactant, having a droplet size of 10 to 100 microns, comprising an (a) aqueous phase comprising water and a polymeric dispersion stabilizer, copolymer of acrylic acid, long chain acrylate; (b) oil phase comprises triglycerides, structurant such as petrolatum, fatty alcohol. See claims 1, 5, column 14-15; column 12,

EXAMPLE column 3, lines 48-55; column 9, lines 30-33. It is also disclosed that the polymeric stabilizer can function as primary emulsifier or surfactant, and thus the composition can be made without conventional surfactants. See column 9, lines 34-37. It is further taught that these compositions made devoid of surfactant will have greater adhesion of the barrier oil to skin, and protection against skin irritants. See column 3, lines 13-18; column 4, lines 36-41.

It would have been obvious to a person of ordinary skill in the art at the time of invention to prepare a wet-skin treatment composition without a conventional surfactant.

One of ordinary skill in the art at the time of invention would have been motivated to prepare a skin-treatment composition as taught by Glenn without a surfactant because Lachhead teaches the process of making similar oil-in-water cosmetic composition without a conventional surfactant.

One of ordinary skill in the art at the time of invention would have been motivated to prepare a skin-treatment composition without any conventional surfactants with the expectation of obtaining a cosmetic composition which will have greater adhesion of the barrier oil to skin, and greater protection against skin irritants.

Applicant's arguments filed 05/12/2006 with respect to the rejections of record in the previous Office Action have been fully considered but are moot in view of the new ground(s) of rejection above. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 7.30 am-3.30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER